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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,483	07/10/2000	Jennie P. Mather	145072000110	1943

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/614,483

Applicant

Mather et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 17, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 29-70 is/are pending in the application.
- 4a) Of the above, claim(s) 7, 14, 15, 22, 29, 30, 37, 43, 44, 48-58, and 68-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 16-21, 23, 31-36, 38-42, 45-47, and 59-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644.

2. Claims 1-23 and 29-70 are pending.

3. Claims 7, 14-15, 22, 29-30, 37, 43-44, and 48-57, as well as newly added Claims 58, and 68-70, stand withdrawn from further consideration by the 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions/species.

Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, 45-47, and newly added Claims 59-67 are under consideration in the instant application.

4. Applicant has indicated that formal drawings will be submitted when the instant application is allowed. However, please note that the filing of corrected drawings may no longer be held in abeyance until such time as claims are found allowable. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

New corrected drawings must be filed with the proper changes incorporated therein. See the PTO Form-948 mailed 1/15/02. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

5. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

6. In view of Applicant's amendment and response, filed 4/25/02, the previous rejections under the second paragraph of 35 U.S.C. 112, and the rejections under the first paragraph of 35 U.S.C. 112 as they pertained to ASC, ESC, ROG, NODD, BR516, and NEP cells, have been withdrawn. Additionally, Applicant's assurances regarding maintenance and availability of the deposited cell line RL-65 (ATCC NO. CRL-10345) have overcome the rejection under the first paragraph of 35 U.S.C. 112 as it pertained to the said cell line.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10 and 40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 14, mailed 1/15/02.

Applicant's arguments, filed 6/17/02, have been fully considered but they are not persuasive. Applicant argues that the specification provides ample teaching regarding a method to obtain BUD and RED cells. It is the Examiner's position, however, that the specification provides only a teaching sufficient to obtain similar epithelial cell lines, but not the specific cell lines of the claims. Accordingly, absent a deposit and appropriate assurances, the rejection must be maintained.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,932,704, in view of U.S. Patent 5,714,385, for the reasons of record as set forth in Paper No. 14, mailed 1/15/02.

Applicant's arguments, filed 6/17/02, have been fully considered but they are not persuasive. Applicant begins by arguing that neither of the reference individually teach or suggest the claimed invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant follows with the argument that neither of the references provide the motivation to combine with the other, and further, that the Examiner has confused motivation to combine and a reasonable expectation of success. It is the Examiner's position that the '704 patent teaches a method of immunization to produce a population of monoclonal antibodies, as well a method

of generating a plurality of monoclonal antibodies, said method employing viable whole cells and antigens in a "native configuration" (column 3, line 14). The secondary reference (the '385 patent) provides the motivation for using ASC or ESC cultured in serum-free media, i.e., enhanced viability and proliferation. Thus, the combined references teach the invention of the instant claims.

11. The following are new grounds of rejection necessitated by Applicant's amendment.

12. Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, 45-47, and 59-67 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) in Claim 1, 11, 31, the recitation of immunizing "repeatedly," and "under conditions which preserve the native configuration of the surface antigens on the cells,"

B) in Claims 61, 64, and 67, the recitation of a method wherein the "repeated introduction into a mammal a plurality of intact cells are without adjuvant."

Applicant asserts that these amendments find support at various sites throughout the specification. However, the Examiner has not found support for the specific new limitations. Regarding repeatedly or repeated immunization, and immunization without adjuvant, the single immunization example of the specification (Example 2) discloses only that mice were immunized with BUD or RED cells "without adjuvant, weekly for 10 to 15 weeks." Said single embodiment is insufficient to support the newly added limitations which would encompass the generic invention of the instant claims. For example, repeatedly or repeated, which can be defined as meaning again and again, would encompass daily, monthly, and yearly immunizations, as well as immunizing from 3 to 100 or more times. Such immunization schedules are not disclosed in the specification. Likewise, the immunization without adjuvant disclosed in the single example with just two cell types cannot now be extended to encompass all the immunizations of Claims 1, 11, and 31. Regarding preserving the native configuration of the surface antigens on the cells,

the vague disclosure at page 3, lines 4-10, cannot support this specific limitation, and Example 2 is silent in this regard.

13. This application contains claims drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
August 29, 2002


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600